

REMARKS

Claims 31-52 are pending in the present application and at issue. Claims 37-41 and 47 are amended to address the Indefiniteness rejection and to correct a typographical error.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. The Rejection of Claims 31-37, 41, 42, 46, 48, and 51 under 35 U.S.C. 112

Claims 31-37, 41, 42, 46, 48, and 51 are rejected under 35 U.S.C. 112 as being indefinite. Specifically, the Office Action objected to the term "enhancing agent" because "it is unclear what the scope of this term is." This rejection is respectfully traversed.

Applicants submit that one of ordinary skill in the art would understand that this term encompasses any compound that enhances the activity of a *Coprinus* peroxidase. The specification discloses a significant number of such enhancers.

However, in order to advance prosecution, the claims no longer use the term "enhancing agent." The scope of the claims has not changed, i.e., the composition recited in claim 31 optionally contains any enhancing agent.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

II. The Rejection of Claims 31-37, 41, 42, 46, 48, 49, and 51 under 35 U.S.C. 112

Claims 31-37, 41, 42, 46, 48, 49, and 51 are rejected under 35 U.S.C. 112 "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Specifically, the Office Action stated the following:

These claims are directed to a genus of methods of killing or inhibiting microorganisms using an antimicrobial composition comprising an enhancing agent and a peroxidase. The specification teaches the structural features defining several sub-genuses of such enhancing agents (i.e., those defined in Claims 8 and 10) and the structures of several specific species within these sub-genuses of such enhancing agents. However, the specification fails to describe any other representative species outside of these sub-genuses by any identifying characteristics or properties other than the functionality of being an 'enhancing agent'. Furthermore, the specification teaches only a single representative peroxidase useful in the methods as claimed and the specification fails to describe

any other representative species of peroxidase by any identifying characteristics or properties other than the functionality of being a peroxidase.

This rejection is respectfully traversed.

It is well settled that the test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the claimed subject matter. *In re Kaslow*, 217 USPQ 1089, 1096 (Fed. Cir. 1983).

As set forth in Federal Circuit decisions, a specification complies with the written description requirement if it provides "a precise definition, such as by structure, formula, chemical name, or physical properties of the claimed subject matter sufficient to distinguish it from other materials." See, e.g., *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398, 1404 (Fed. Cir. 1997); *Enzo Biochem v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002).

Applicants submit that the specification complies with the written description requirement.

The claimed invention is drawn to methods of killing or inhibiting a microorganism, comprising contacting said microorganism with a composition comprising a peroxidase produced by or derived from *Coprinus* and a hydrogen peroxide or a source of hydrogen peroxide. The specification describes a DNA sequence encoding a *Coprinus* peroxidase and one of ordinary skill in the art would appreciate that other *Coprinus* peroxidases would have homologous amino acid sequences. The specification also describes a number of peroxidase enhancing agents. Applicants therefore submit that the specification of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the claimed subject matter.

The Office argues that "multiple different species of an enzyme with unrelated or only low structural similarity to each other within an organism is frequent." This is respectfully traversed.

The Office has provided no evidence that *Coprinus* peroxidases are not structurally similar. To the best of our knowledge, there are only two *Coprinus* peroxidases, one from *Coprinus cinereus* and the other from *Coprinus macrorhizus*. As shown in the attached abstract of Kjalke et al. (Biochim. Biophys. Acta, 1992, 1120(3): 248-56), the two peroxidases likely have the same amino acid sequence.

Moreover, claim 32 is drawn to the use of a *Coprinus cinereus* peroxidase and claim 33 is drawn to the use of a peroxidase of a specific *Coprinus cinereus* strain.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

III. The Rejection of Claims 31-37, 41, 42, 46, 48, 49, and 51 under 35 U.S.C. 103

Claims 31-37, 41, 42, 46, 48, 49, and 51 are rejected under 35 U.S.C. 103 as being unpatentable over Johansen (WO 96/06532) in view of Schneider et al. (WO 96/10079). This rejection is respectfully traversed.

Schneider et al. disclose peroxidase systems comprising an enhancer.

However, Schneider et al. also do not teach or suggest the use of peroxidases to kill or inhibit microorganisms.

Johansen discloses compositions capable of killing microbial cells or inhibiting microorganisms. The component which kills or inhibits the microorganisms is a basic protein or peptide of biological origin, e.g., protamine or protamine sulphate. Johansen further discloses that the composition may further comprise a cell wall degrading enzyme and/or an oxidoreductase such as a peroxidase.

In Example 2, Johansen compares the effect of protamine and several enzymes, including a peroxidase enzyme system (i.e., lactoperoxidase/glucose oxidase). The results obtained by Johansen are summarized at page 21 as follows:

It is demonstrated that protamine and protamine sulfate are very effective substances for inhibiting all the tested strains, whereas polyarginine is effective for inhibiting all strains but *Pseudomonas* spp. Apart from the effect of lysozyme on *Listeria monocytogenes*, none of the tested enzyme showed any effect.

The results are shown in Table 4, which show that the peroxidase enzyme system was not effective in killing or inhibiting microorganisms. A footnote to Table states that "The lactoperoxidase system was effective for maximum 70 hours. The definition of MIC require[s] an inhibition of at least 100 hours." Based on the description of the results, Applicants submit that this phrase should be interpreted to mean that the haloperoxidase system was "active" for 70 hours. It does not mean that the peroxidase system was effective for killing or inhibiting microorganism. Otherwise, one would expect that the results would be provided in the specification. Thus, Johansen does not teach or suggest the use of peroxidase systems for killing or inhibiting microorganisms.

Moreover, the instant specification shows that *Coprinus* peroxidases have a significant effect in killing or inhibiting microorganisms. See, e.g., the results on page 46 in the specification.

There is no suggestion in the cited references that *Coprinus* peroxidases are superior antimicrobial agents. Thus, these results are surprising and unexpected.

The Office states that "Johansen clearly suggest that the combination of protamine and a peroxidase system is synergistically effective (see Example 4) in killing or inhibiting microorganisms. Applicants' claims in no way exclude the inclusion of protamine in the compositions. As such the skilled artisan having the disclosures of both Johansen and Schneider would have been motivated to make detergent compositions including enhancing agents, a peroxidase system, protamine and other standard detergent components." This is respectfully traversed.

Johansen provide no data demonstrating that there is synergism between the peroxidase system and protamine. In any event, even if there is synergism, that does not make the use of *Coprinus* peroxidases for killing or inhibiting microorganisms obvious. Johansen states that the peroxidase system alone has no effect. Since a *Coprinus* peroxidase has a significant anti-microbial effect, one of ordinary skill in the art would expect that the combination of a *Coprinus* peroxidase and protamine would have a significantly greater effect than the combination of Johansen's peroxidase system and protamine.

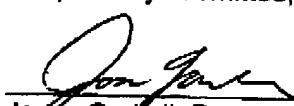
For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: June 14, 2004



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